BEFORE THE ARIZONA MEDICAL BOARD

In the Matter of **F. HUGO VILLAR-VALDES, M.D.** Holder of License No **9674** For the Practice of Allopathic Medicine In the State of Arizona.	Board Case No. MD-04-0625B **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER** (Letter of Reprimand)

The Arizona Medical Board ("Board") considered this matter at its public meeting on June 7, 2006. F. Hugo Villar-Valdes, M.D., ("Respondent") appeared before the Board for a formal interview pursuant to the authority vested in the Board by A.R.S. § 32-1451(H). The Board voted to issue the following Findings of Fact, Conclusions of Law and Order after due consideration of the facts and law applicable to this matter.

FINDINGS OF FACT

1. The Board is the duly constituted authority for the regulation and control of the practice of allopathic medicine in the State of Arizona.

2. Respondent is the holder of License No. 9674 for the practice of allopathic medicine in the State of Arizona.

3. The Board initiated case number MD-04-0625A after being notified of a medical malpractice settlement involving Respondent's care and treatment of a forty-two year-old female patient ("TS"). A July 30, 2002 mammogram demonstrated TS had numerous fine linear indistinct calcifications in the upper outer quadrant of her left breast extending over a six centimeter area suspicious for extensive ductal carcinoma in situ ("DCIS"). On August 2, 2002 Respondent performed wire localization of the abnormality followed by a surgical excision of the tissue surrounding the wire. Respondent's operative note described a periareolar incision through which Respondent excised a block of tissue around the tip of the wire. Respondent's operative report states he obtained X-ray confirmation of the specimen and he could identify at least three or four

microcalcifications on the monitor. The dictated radiology report of the wire localization procedure states the final images demonstrated the wire was approximately two centimeters superior to the calcifications.

4. Pathologic examination of the excised tissue demonstrated fibrocystic changes without evidence of malignancy. Respondent ordered a follow-up mammogram be performed in six months. A February 21, 2003 mammogram demonstrated numerous heterogeneous pleomorphic linear indistinct calcifications suspicious for a malignancy. A biopsy was performed on March 7, 2003 and demonstrated high grade DCIS with comedo necrosis. On April 14, 2003 Respondent performed bilateral simple mastectomy and a plastic surgeon performed a reconstruction. Pathology demonstrated a 4.2 centimeter infiltrating ductal carcinoma and TS underwent left axillary dissection on May 2, 2003 that demonstrated four out of seven lymph nodes were positive for carcinoma.

5. Respondent testified he failed to recognize during the wire localization procedure the wire was two centimeters away from the main lesion. Respondent noted he saw four microcalcifications on his specimen and he did recognize he missed the main specimen about three weeks later when he met with the radiologist. Respondent noted TS cancelled two scheduled appointments to come to his office after the initial biopsy and then came to his academic office where he did not have access to her record. Respondent noted TS and her husband worked in the hospital and felt free to come and see him at this office. Respondent testified he told TS and her husband he thought he had missed and suggested a new biopsy, but TS elected to go to the Fox Chase Cancer Center ("Fox Chase") for a second opinion. Respondent noted he did not document this conversation because he was not seeing TS in a regular clinical setting. Respondent testified TS elected to have the six-month follow-up and selected him as her main surgeon for the next two consecutive surgeries.

6. The Board noted TS underwent four procedures - the needle localization procedure that failed; a repeat biopsy and a repeat lumpectomy; dissection of the lymph nodes and the mastectomy. Respondent agreed there were basically four procedures. The Board asked how many procedures are done in the normal course of treating breast disease. Respondent testified when there is in situ cancer it could be two, three millimeters or it could be very tiny or it could be very extensive, as it turned out to be in TS. Respondent noted the usual way things evolve is the patient gets the stereotactic biopsy done by a radiologist and, if in situ cancer is identified, a wider biopsy is done to see the extension of the cancer - if there is more advanced cancer.

7. The Board asked if it was unusual that TS underwent three subsequent procedures after the initial missed biopsy. Respondent testified sometimes after lumpectomy where the carcinoma is seen as extensive patients want to preserve the breast so he may do a lumpectomy in the hopes of having negative margins and being able to preserve the breast. In sum, Respondent noted it was not uncommon for a patient to have perhaps two lumpectomies after initial biopsy shows intraductile carcinoma. Respondent noted intraductile carcinoma cannot be palpated. The Board noted on TS's mastectomy the specimen was shown to be four centimeters and would seem it could have been palpated. Respondent testified this was not necessarily so and if TS has a different kind of cancer called lobular cancer nothing can be felt and the mammogram may grossly underestimate, so it is much more complex than just thinking that you have a four centimeter area of intraductile cancer and that you cannot palpate it. Respondent noted this is the irony of this cancer.

8. The Board asked if the standard of care at the time of TS initials biopsy required a frozen section read while TS was still anesthetized. Respondent testified it did not because it was already known she had cancer and he wanted to know if the margins are clear and it is very difficult to assess so many margins in a volume of breast tissue so frozen biopsy is not done

anymore. Respondent noted now lumpectomies are performed and the specimen is covered with ink and the pathologist looks at the specimen and sees the tumor by the ink. If the pathologist says the margins are positive they will re-ink the specimen so they know which margin is positive or where it is located.

The Board noted one of the allegations of the complaint against Respondent was that not enough breast tissue was removed during the initial biopsy and asked what would be enough tissue. Respondent testified it was relative and TS had a small breast and he did not want to disturb the breast if he did not have proof it was malignant, so he was balancing cosmesis with diagnosis and it is difficult to prove what is enough and, if the diagnosis is missed, the allegation is always that not enough was taken. Respondent noted he tries to work around the tip of the wire, and if the wire is in the right place and there is a tumor, you get negative margins and that is the goal. Respondent noted unfortunately in TS's case, he went around the wire, but the wire was in the wrong place and he missed the tumor completely.

The Board confirmed the radiologist places the wire and asked whose responsibility it is to make certain the wire is in the appropriate position. Respondent testified it was the radiologist's responsibility and if it is not in the proper place his usual radiologist will call him or put a note in the X-ray that tells him where the wire is. Respondent noted the radiologist who assisted with TS's procedure was not a dedicated mammographer. The Board confirmed Respondent's position was that the radiologist was responsible for the inappropriate biopsy Respondent performed. Respondent testified the radiologist was responsible because the wire tells Respondent where to go. The Board asked whether Respondent was responsible because he was the one who performed the surgery. Respondent testified his duty is to make sure he can correlate the microcalcification with the position of the wire and be sure he has microcalcifications in his X-ray specimen. Respondent noted there was no question he underestimated the deviation

of the wire. The Board asked who was responsible for that. Respondent testified it was a shared responsibility.

9. The Board asked if the six month delay in TS coming back to Respondent was her choice or the recommendation of Fox Chase. Respondent testified it was TS's choice after going to Fox Chase. The Board asked if the recommended treatment was to wait six months for a repeat biopsy or was it TS's choice to wait six months. Respondent testified sometimes he decides and in TS's case he thought he should have been more forceful in having her undergo the repeat biopsy. The Board asked if TS's course was affected by the eight month delay. Respondent testified he did not think that question could be answered with any objectivity because the rate at which cancer grows in a patient is so different and some cancers metastasize from the first time the cell becomes malignant and some cancers can stay or divide so low the metastasis rate is very slow. Respondent testified he did not think it can be said definitively that during the eight month delay the cancer moved from the breast to the lymph node.

10. The Board asked if it made sense empirically that the longer Respondent waits before doing a re-biopsy there is more of a chance for metastasis. Respondent testified medicine was not like that, but noted the earlier a diagnosis of malignancy is made the better. However, Respondent noted that does not take away all the chance of having metastasis. The Board asked if Respondent believed an earlier diagnosis would have been better for TS. Respondent testified he did not think so.

11. The Board confirmed that TS was relatively small in stature, including breast size and that when Respondent initially saw her he could not feel a breast mass in the area where the problem was. The Board asked if Respondent noted the radiologist reported in the mammogram report he could feel a mass. Respondent testified he did, but neither he nor TS could feel it. The Board noted the mammogram reported an area of abnormal microcalcifications extended over a six centimeter area giving Respondent a large target in a relatively small breast. Respondent

testified this is why he felt satisfied when he saw microcalcifications in his specimen. The Board asked why Respondent elected to do a needle localization and open biopsy. Respondent testified he did so because he did not want to miss it and that is the irony of this whole case. Respondent noted he figured if he got a negative biopsy with stereotactic biopsy that takes such a tiny piece of tissue it would not give him enough reassurance that TS did not have cancer, so he figured there would be less chance of missing the diagnosis by doing it open.

12. The Board asked if Respondent performed Mammotome biopsy. Respondent testified he did not, but the radiologists do. The Board asked if Respondent believed Mammotome biopsy is an accurate way to clarify calcifications in a breast that does not have a palpable mass. Respondent testified he thought it was a very accurate way because you can see where the tip of the needle is and the accuracy is very good. The Board asked if Respondent considered referring TS for Mammotome biopsy. Respondent testified TS wanted an open biopsy. Respondent noted TS was an oncology nurse and came in on a Thursday wanting the biopsy done on Friday before she left for vacation. The Board asked what Fox Chase recommended to TS. Respondent testified he was told they wanted to wait six months and see, but he did not see any written recommendation or any document from Fox Chase. The Board noted when the repeat mammogram was done eight months later the calcifications had enlarged or increased in number and Respondent referred TS to the radiologist for a stereotactic biopsy.

13. The Board asked if when Respondent did the bilateral mastectomies he still felt he was dealing exclusively with a non-invasive cancer. Respondent testified he did because the appearance on X-ray was intraducticle and there was not a mass, there was not a density, it was just scattered calcium everywhere. Respondent noted this was why he did not think he could do a lumpectomy either and was worried he would have positive margins and that is why he recommended a mastectomy rather than a lumpectomy. Respondent noted the frustration is by the abnormality on the X-ray he still missed the infiltrating component. The Board noted

Respondent's missing that necessitated yet another surgery, a fourth surgery to do an axillary sampling that maybe could have or should have been done at least at the time of the bilateral mastectomy. Respondent testified this was correct and this is his frustration. Respondent testified it looked like intraductile carcinoma extensive all the time from the first day he saw TS until the day he did the mastectomy.

14. The Board noted once the diagnosis of DCIS was made by stereotactic needle biopsy the tumor was high grade and was comedo carcinoma. The Board asked if Respondent would recommend sentinel node biopsy with DCIS with such a presentation. Respondent testified he routinely would and he does not really remember why he did not do it with TS because it would be a high probability it could be a positive lymph node. The Board confirmed it would have saved TS from the fourth surgery. Respondent testified there were several issues involved in TS's care; the difficulties in dealing with breast issues, the inaccuracies despite all the technology, and having a patient who works in the same hospital whose husband is a physician made things more complicated because his normal way of making decisions was broken either because TS insisted or her husband insisted.

15. The Board noted it appreciated Respondent's candor and that it was mitigating both that the usual radiologist was unavailable resulting in the needle being placed in a suboptimal position by a substitute radiologist and that Respondent agreed he performed an inadequate biopsy. The Board also noted it was concerned Respondent knew there was a suboptimal biopsy but did not document his conversation with TS informing her she needed a repeat biopsy and did not aggressively attempt to get TS back to his office.

16. The standard of care requires a surgeon performing a wire localized breast biopsy to perform an adequate biopsy and, if the surgeon recognizes the biopsy is inadequate, to aggressively pursue a repeat mammogram.

17. Respondent deviated from the standard of care because he performed an inadequate biopsy, and although he recognized he had done so, he did not aggressively pursue a repeat biopsy.

18. TS's diagnosis of breast cancer was delayed for eight months and she was subjected to at least one additional procedure.

CONCLUSIONS OF LAW

1. The Arizona Medical Board possesses jurisdiction over the subject matter hereof and over Respondent.

2. The Board has received substantial evidence supporting the Findings of Fact described above and said findings constitute unprofessional conduct or other grounds for the Board to take disciplinary action.

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1401(27)(q) ("[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public").

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law,

IT IS HEREBY ORDERED:

Respondent is issued a Letter of Reprimand for performing an inadequate biopsy and for failing to aggressively pursue repeat biopsy when he recognized the biopsy was inadequate.

RIGHT TO PETITION FOR REHEARING OR REVIEW

Respondent is hereby notified that he has the right to petition for a rehearing or review. The petition for rehearing or review must be filed with the Board's Executive Director within thirty (30) days after service of this Order. A.R.S. § 41-1092.09(B). The petition for rehearing or review must set forth legally sufficient reasons for granting a rehearing or review. A.A.C. R4-16-102. Service of this order is effective five (5) days after date of mailing. A.R.S. § 41-1092.09(C). If a

petition for rehearing or review is not filed, the Board's Order becomes effective thirty-five (35) days after it is mailed to Respondent.

Respondent is further notified that the filing of a motion for rehearing or review is required to preserve any rights of appeal to the Superior Court.

DATED this 11th day of August, 2006.

THE ARIZONA MEDICAL BOARD

By _____
TIMOTHY C. MILLER, J.D.
Executive Director

ORIGINAL of the foregoing filed this 11th day of August, 2006 with:

Arizona Medical Board
9545 East Doubletree Ranch Road
Scottsdale, Arizona 85258

Executed copy of the foregoing mailed by U.S. Mail this 11th day of August, 2006, to:

Hugo Villar-Valdes, M.D.
Address of Record

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